

NIH POLICY MANUAL

55808 - ESTABLISHMENT AND DOCUMENTATION OF FILES AND OTHER RECORDS, INCLUDING MONITORING ACTIONS, FOR NIH GRANT PROGRAMS

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A. Purpose:

In order to maintain complete, orderly, and chronological records of grant programs and individual grants, including a history of the peer review and various administrative actions associated with a given grant, this chapter sets forth the minimum requirements for the establishment and documentation of files and other records, including monitoring action, for NIH grant programs.

B. Applicability:

This chapter is applicable to all NIH grant programs.

C. References:

1. NIH Manual Chapter [4700](#), Notice of Grant Award
2. NIH Manual Chapter [5805](#), Closeout of NIH Grants
3. NIH Manual Chapter [5806](#), Delinquent Reports - Discretionary Grants
4. NIH Manual Chapter [5807](#), Submission and Acceptance of Revised Reports of Expenditures

D. Policy:

The Grants Management Officer (GMO) of each awarding unit is responsible for assuring that complete and up-to-date program information files and official grant files for individual projects are established and maintained. These files shall be under the direct control and responsibility of the Grants Management Officer. Monitoring duties shall be the responsibility of at least one grants management and one program official for each grant.

E. Implementation:

1. Program Information Files
 - a. Grants Management Officers shall establish and maintain an official program information file in their own offices or some other publicized central location in the Bureau, Institute, or Division (BID). A separate

file folder shall be established for each program and/or mechanism of support in the BID. (Use the DRG Activity Codes to determine program involved.)

- b. When the BID initiates a new program a folder should be established containing announcements, guidelines, and any other information peculiarly pertinent, such as earmarked funds, special receipt dates, arrangements for review, etc.
- c. Each folder should have the documents or information listed below in d. insofar as they exist or are applicable. Where a single document (e.g., Code of Federal Regulations, Title 42, Part 52) is applicable to more than one program of the BID, a single copy can be maintained with reference in the individual file as to its applicability.
- d. Items in program information files should include, as applicable:
 - (1) Program title
 - (2) DRG activity code
 - (3) Catalogue of Federal Domestic Assistance number
 - (4) Citation of legislative authorization (USC)
 - (5) Citation of applicable Federal Regulations
 - (6) Announcements (copy) (e.g., Federal Register, NIH Guide for Grants and Contracts, BID announcement)
 - (7) Citation of all applicable guidelines and/or policy statements (e.g., the PHS Grants Policy Statement and/or other guidelines - include one copy of the latter)
 - (8) Authorized deviations from (7)
 - (9) Description of any special review procedures not addressed in (6)
 - (10) Copy of any correspondence or other document from Congress, Office of General Counsel, etc., concerning the program, but not specifically about an individual grant
 - (11) Copy of any pertinent GAO, Audit, and Congressional Committee reports not specifically about an individual grant e. Program information files shall be reviewed at regular intervals to assure that they are complete and current.

2. Official Grant File System

A separate file folder must be established and maintained centrally within the

BID for each grant project and shall contain all significant documents which pertain to the individual grant-supported project. Pertinent material should be filed in a timely manner and maintained chronologically through final closeout.

a. As applicable, an individual file folder shall include the following:

- (1) Application for each budget period - as well as any subsequent revisions or additions
- (2) Summary Statement for each competitive review
- (3) Grants Management/ICMS Worksheet (Form NIH 705) for each award (completed and signed original)
- (4) Cost-sharing Agreement (only for project-by-project method)
- (5) Human Subject Certifications
- (6) Notice of Grant Award
- (7) Financial Status Reports (expenditures reports)
- (8) Progress Reports (annual and final)
- (9) Invention Statements
- (10) Special documents (e.g., A&R plans and specifications, third party agreements, relinquishment statements, pertinent audit material, appeal material)
- (11) Staff on-site visit reports
- (12) Correspondence and memoranda
- (13) Closeout documentation In addition, for manpower/training grants and awards:
 - (1) Activation Notices ("F" programs only)
 - (2) Statement of Trainee Appointment (Form PHS-2271)
 - (3) Signed Payback Agreements
 - (4) Termination Notices
 - (5) Annual Payback Activities Certification Forms

b. Preceding the preparation of each Notice of Grant Award, the file will be reviewed to insure that all required documents are in hand, and the file initialed by the reviewer and dated to signify completeness.

c. No Notice of Grant Award may be issued until all required documents are on file. For active grants, no noncompeting continuation nor competing renewal award may be made unless required Financial Status Reports have been received.

d. For closeout of grants, the procedures outlined in NIH Manual Chapter 5805 shall be followed.

3. Institutional Information Sources

The NIH has a number of sources of detailed information concerning institutions and organizations participating in the NIH's extramural programs. This information is available to BID staff and should be utilized when needed. The information and location are:

a. Indirect Cost Rate File

An up-to-date collection of institutional indirect cost rate agreements. This file provides institution's name, entity identification number, city and state, type rate, effective period, indirect cost rate (%), locations (on-campus, off-campus, other sites), base description, treatment of fringe benefits, fringe benefit rates, and special remarks pertaining to treatment of costs within institutional accounting systems. This file is distributed to BIDs on a monthly basis. Further information regarding this file may be obtained from the Accounting and Indirect Cost Section (AICS), Federal Assistance Accounting Branch (FAAB), Division of Financial Management (DFM).

b. Patient Care Cost Rate Files

An up-to-date collection of institutional Research Patient Care Rates. This file provides institution's name and address, type rate, effective period, inpatient routine care rates (percentages), inpatient ancillary service rates (percentages) such as operating room, anesthesiology, laboratory, drugs, physical therapy, oxygen therapy, etc., and any optional remarks deemed necessary by the regional negotiators. Information is available upon request to the AICS, FAAB, DFM.

c. Institutional Catalogue Library and Institutions Research

A complete up-to-date collection of grantee institutional catalogues and ancillary information is maintained in the Reports, Analysis, and Presentation Section, Statistics and Analysis Branch, DRG, Room 1A18, Westwood Building.

d. Institution Profile File (IPF)

A sub-file in the NIH IMPAC data system. The IPF is the computer-based central registry of selected data on all applicant institutions dating

from 1945. It provides name, state, city, area, Congressional District, PHS region, type of organization, ownership or control, human subjects assurance code, etc. Information is available upon request from: See c. above.

e. Successor in Interest and Name Change Agreements

Centralized information is available from the Grants Policy Office, Office of Extramural Research and Training (OERT), NIH.

f. New Applicant Organizations

In those cases where a new or potential grantee institution is identified, awarding unit staff should notify the Grants Policy Office, OERT, which will act as the single NIH focal point for distribution of general information to the applicant institution. Basic information concerning the institutional administrative and fiscal management responsibilities associated with NIH grant-supported programs will be conveyed principally through a memorandum (See Illustration 2) which cites some of the more important grants management policy issuances, HHS offices having responsibility for certain administrative functions, and sources of continuing information. The Grants Policy Office, OERT, will assist in obtaining answers to any questions from the awarding units concerning management capabilities, organizational arrangements, etc., of new or unknown applicant organizations.

4. Monitoring Duties

Such duties are to be assigned to and performed by at least one grants management and one program official for each funded grant. This shared responsibility is in keeping with NIH's "team" approach to grant administration and the dual signature feature of NIH's award notices. If BID staff other than those whose signatures appear on award notices have primary responsibility for business management and program management aspects respectively, then their names and telephone numbers should be provided to each grantee at time of award (specified on the Notice of Grant Award or included on a supplemental notice) or separately conveyed by letter or other notice. For each duty listed below, the designated official shall have primary responsibility for performing the minimum monitoring actions listed:

a. Ensuring timely receipt of all required reports - Grants Management Office.

b. Review Financial Status Reports (expenditures reports) - Grants Section, FAAB, DFM, and BID Grants Management Office. All Financial Status Reports will be initially received and centrally processed by DFM, to ensure that reports are complete and accurate. On a monthly basis DFM notifies grantees of delinquent Financial Status Reports. DFM and the GMOs will coordinate the action(s) necessary to

resolve all matters of questionable or inappropriate expenditures or obligations. As part of the preaward review of non-competing continuation or competing renewal applications, the GMO must obtain all delinquent reports or notify the grantee that further awards will not be made until the delinquent reports are received.

c. Review of Progress Reports (annual and final) - Program Official. These reports shall include at a minimum (a) actual accomplishments toward meeting project goals, (b) reasons for not meeting desired goals, (c) plans for activities during the coming year.

d. With respect to items (1) through (6) below, the review of business management concerns shall be the responsibility of grants management officials and the review of programmatic concerns shall be the responsibility of program officials:

(1) Audit reports which are pertinent to a specific active grant or a grant not yet closed out

(2) Site visit reports (If neither a designated grants management official nor a designated program official was able to participate in the visit, such an official must base his or her review upon the report written by the responsible person who participated in the visit or upon an interview with such a person.)

(3) Progress report portions of continuation and competing renewal applications

(4) Correspondence from grantees or third parties in which information on grant performance is requested and provided

(5) Memoranda of significant telephone conversations requiring specific monitoring actions

(6) Closeout documents (See NIH Chapter [5805](#).)

e. Other responsibilities for considerations such as human subject involvement, use of animals, inventions, cost-sharing, patient care costs, alterations and renovations, etc., will be individually assigned or shared by grants management and program officials depending on the specific circumstances.

The aforementioned monitoring duties are required actions to be performed continuously and may not be omitted. For example, if a report is required from a grantee, its receipt must be checked and upon receipt it must be reviewed. The action shall be performed as soon as possible after the due date, date of receipt, or other occasion. It should be noted that in many cases the same item will require separate monitoring reviews by two persons, a grants management official and a

program official.

f. The Fiscal and Monitoring Statement to be used by NIH to document the fact that all fiscal, administrative, and other preaward actions have been completed (or if not completed, conditioned as a term of award) is Form NIH 705, "Grants Management/ICMS Worksheet" (See Illustration 1). This form also is to be used to document postaward actions such as receipt and review of Financial Status Reports, progress reports, invention statements, etc., from prior periods. The use of this form is mandatory except for individual fellowship and career awards. If deemed necessary, awarding units may at their discretion, use additional worksheets or other monitoring records to supplement Form NIH 705; however, the use of this standard form by all NIH awarding units is required as a minimum.

The original copy of Form NIH 705, completed and signed by either the Grants Management Officer or his or her designated staff member, must be maintained in the official file folder as evidence that all required fiscal, administrative, and monitoring actions have been satisfied. A Notice of Grant Award may not be processed unless a copy of this form accompanies the other necessary authorizing documentation to the Division of Financial Management.

F. Effective Date:

This policy is effective on date of release.

G. Additional Information:

For further information on this chapter, contact the Grants Policy Office, Office of Extramural Research and Training, 496-5967.

H. Additional Copies:

For copies of this manual chapter send a Form NIH 414-5, "Request for Manual Chapter" to the Printing and Reproduction Branch (P&RB), DAS, Building 31, Room B3BE07.

Refer to Hardcopy Illustration 1

Refer to Hardcopy Illustration 2